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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,107	04/12/2004	Philip A. Carpino	PC25541A	5444

28523 7590 09/12/2005

PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
EASTERN POINT ROAD
GROTON, CT 06340

EXAMINER	
OWENS, AMELIA A	
ART UNIT	**PAPER NUMBER**
1625	

DATE MAILED: 09/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/823,107	CARPINO ET AL.	
	Examiner	Art Unit	
	Amelia A. Owens	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,13-17,31,33,36-38,45,46,51,52,57,58 and 62-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,13-17,31,33,36-38,45,46,51,52,57,58 and 62-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

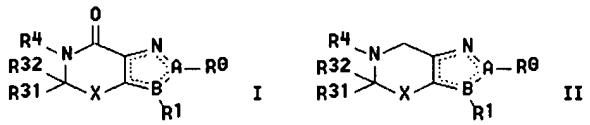
1. Claims 5-12,18-30,32,34,35,39-44,47-50,53-56,59-61 have been canceled. New claim 77 added. Claims 1-4,13-17,31,33,36-38,45-46,51-52,57-58,62-77 are pending.

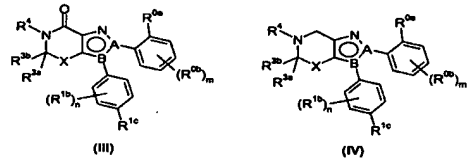
Information Disclosure Statement

2. the examiner has considered the IDS.

Election/Restrictions

3. Applicant's election without traverse of Group II, claims 12-17, and claim 77 and claims 1-4,13-17,31,33,36-38,45,46,51,52,57,58 (in part) drawn to compounds below (also included are compounds of formula III and IV) where A is nitrogen, B is carbon and X is C(R2a)R2b in the reply filed on June 22, 2005 is acknowledged.





Applicants' requested rejoinder of method claims according to MPEP 821.04.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1,4,13,31,33 are rejected under 35 U.S.C. 102(b) as being anticipated by Duplantier et al CA 129:49198 (@ page 8 of search notes) that teach species according to the invention formula I. See RN 6497-40-1. Note R4 is phenyl (aryl); R3b(R3a) is hydrogen; X is C(R2a)R2b where R2a(R2b) is hydrogen; Ro is 4-fluorophenyl (sub. Aryl); R1 is CH2CH2(R1a) where R1a is hydrogen.

5. Claims 1,4,13,31,33 are rejected under 35 U.S.C. 102(b) as being anticipated by Ciba Ltd CA 65:12344 (@ page 9 of search notes) that teach species according to the invention formula I. See for example, RN 6469-04-1; RN6497-31-0.

6. Claims 1,4,13,31,33 are rejected under 35 U.S.C. 102(b) as being anticipated by Duplantier CA 122:239696 (@ page 17 of search notes) that teach species according to the invention formula I. See RN 162142-37-2; RN 162142-38-3.

7. Claims containing formulas III and IV are not included in the above rejections as the formulas require positions R1/Ro to both be phenyl and the prior art neither teaches nor suggests such substitution. Thus, claims 45-46,51-52,57-58,77 contain subject matter neither taught nor suggested by the prior art.

8. Compounds of formula II are not included in the above rejection as the prior art neither teaches nor suggests compounds that the carbon adjacent to the ring nitrogen contains only hydrogen, all other substituents as defined. See for example, Bosch et al CA 93:168264.

or as defined by R3a/R3b,

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-4,13-17,31,33,36-38,45,46,51,52,57,58,62-77 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The nature of the invention: The nature of the invention is the method for treating a disease, condition or disorder modulated by a cannabinoid receptor antagonist comprising administering a compound of claim 1 alone or in combination with an additional pharmaceutical agent; compounds of formula III and IV. See claims 1 and 45 for example.

The state of the prior art and predictability: The state of the prior art is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific disease). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of

ordinary skill in the art from accepting any therapeutic regimen on its face. It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F. 2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instantly claimed invention is highly unpredictable given modulation of a receptor includes inhibition and enhancement.

The exact role of the cannabinoid receptor is still under investigation. Further, there is more than one (1) cannabinoid receptor. See Barth et al 'The development of cannabinoid antagonists' PubMed ID: 10469889 that teach two (2) cannabinoid receptors. Which receptor is applicants' modulating? Moreover, at the time of the invention, there is no umbrella drug known for treatment of all disorders, conditions, diseases related to cannabinoid receptors. One of ordinary skill in the art would have no basis to extrapolate results to compounds structurally removed from those of the prior art.

Further, applicants' are combining the claimed compound with additional compounds belonging to 'classes' of compounds. See claims 63,64 for example.

Guidance and working examples: The tests beginning at page 75 are noted. It is not clear that any of the assays correlate to cannabinoid receptor modulation and any diseases, disorders, condition. There is no evidence of functional treatment, i.e. no correlation to treatment in humans. Applicants have not shown any of the claimed compounds effective via modulation of a cannabinoid receptor for applicants claimed purpose. Applicants' assertions either that the compounds would be effective *or* that the compounds are effective are not enough. Moreover, applicants are claiming ALL diseases, disorders, conditions, known to be associated with

modulation of cannabinoid receptors AND such future diseases, disorders, conditions associated with modulation of cannabinoid receptors and such is wholly inoperable.

Thus, the specification fails to provide sufficient support of the broad use of the compounds of claims 1 and 45 for the treatment of any disease. As a result necessitating one of ordinary skill to perform an exhaustive search for which diseases can be treated by which compound of claims 1 and 45 in order to practice the claimed invention.

10. Claims 68 and 72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement because claims without any limitation of what is the second ingredient, renders the scope wholly inoperable. The second ingredient can be synergistic, additive, antagonistic, completely blocking the activity of the first ingredient. Therefore, such composition has an operability which cannot be ascertained.

11. Claims 62-76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims/specification lists nicotine receptor partial agonist, opioid antagonist, dopaminergic agent, etc, which can be administered with in combination with the claimed compounds. The listing lacks enablement since the specific dosage change required for the instant compound were not disclosed. In addition, the claims encompass any and all nicotine receptor partial agonist, opioid antagonist, dopaminergic agent, etc, including as yet to be discovered compounds and such is wholly inoperable.

12. Claims 62-~~77~~ 76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Method claims 62-76 encompass as yet unidentified diseases, disorder, conditions associated with the cannabinoid receptor, a description of which is not found in the specification. Further, there are two receptors, (See Barth et al 'The development of cannabinoid antagonists' PubMed ID: 10469889 that teach two (2) cannabinoid receptors). Which receptor is applicants' modulating?

Method claims 62-76 encompass as yet unidentified cannabinoid receptors, a description of which is not found in the specification.

The claims/specification lists nicotine receptor partial agonist, opioid antagonist, dopaminergic agent, etc, which can be administered with in combination with the claimed compounds. Such listing provided no description or guidelines as to 'how' to operate the method employing any and all 'additional pharmaceutical agent'.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 63,64,69,70,73,74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms analog and agent are indefinite. Is it functionally similar? Is it structurally close?. The metes and bounds of what would be within the scope of the claims being encompassed by the term 'analog' or 'agent' cannot be ascertained.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

14. Claims 68,72 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The claims are drawn to multiple active ingredient composition without naming what the second ingredient is. The second ingredient can have similar activity, opposite activity or completely unrelated activity. Thus, the utility of the combination is unknown and unlimited. Since no guidelines can be given to such unlimited composition, the claims are wholly inoperable in absence of ~~nay give~~ any given nature of the composition.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amelia A. Owens whose telephone number is 571-272-0690. The examiner can normally be reached on Monday - Friday from 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMELIA AVERILL OWENS
PRIMARY EXAMINER